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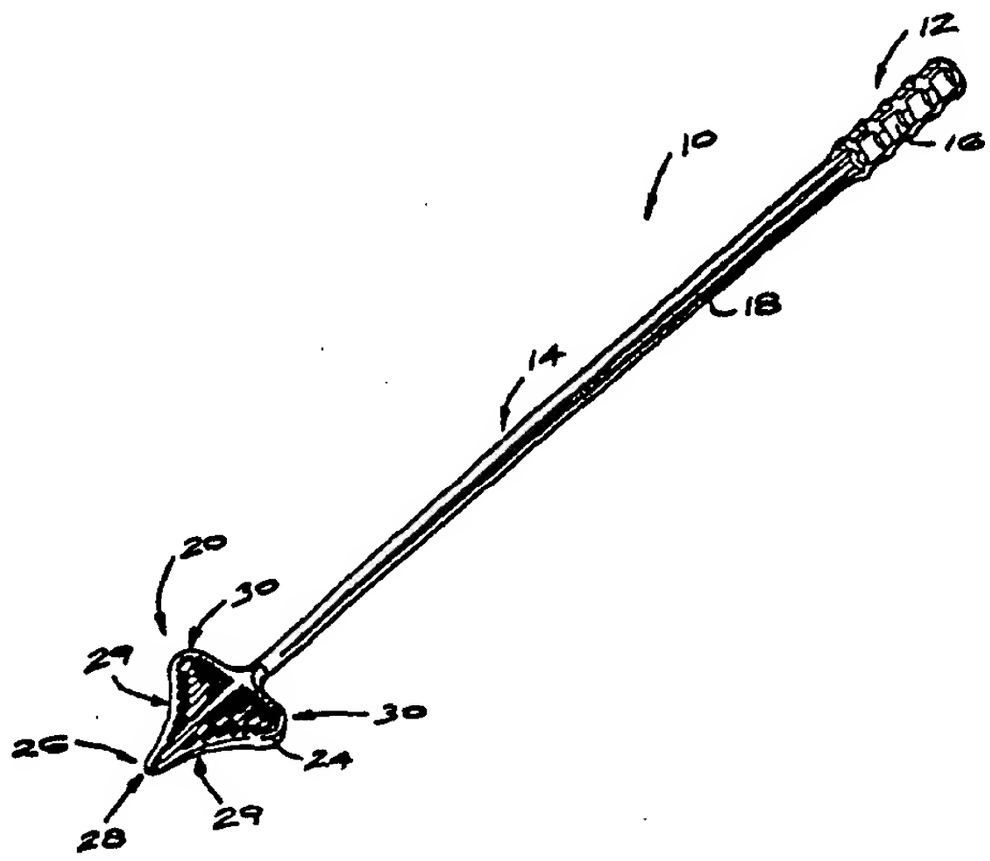
(54) Title: MEDICAL SPATULA



(57) Abstract

This invention relates to a medical spatula that finds particular application as a spatula for exfoliative cytology, such as cervical or vaginal smear tests (PAP tests). The spatula of the invention comprises a grip, made up of a hand grip (12) and an insertion rod (14), and a substantially planar blade (20). The blade (20) consists of an open loop that defines the rim (24) of the blade (20) and a lattice of spaced apart bars (22) that arise from the peripheral rim (24) and transect the body of the blade (20). When adapted for use as a cervical spatula (10), the periphery of the blade is shaped to conform to the shape of the average cervix. The spatula (10) is integrally formed from a resiliently deformable material such as injection moulded plastics, preferably low density polyethylene.

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MEDICAL SPATULA

Background to the invention

This invention relates to a medical spatula.

The spatula finds particular application as a spatula for exfoliative cytology and it will be described with reference to a cervical spatula by way of example.

The so-called PAP test, named after the Greek-American physician George Papanicolaou who developed the vaginal smear test in 1928 to diagnose cervical cancer, is probably the most widely used example of exfoliative cytology. PAP tests are normally performed using a hand held scraper or spatula that is used to scrape off the outer cells of the cervix prior to a transfer of the cells to a glass slide for microscopic evaluation.

The spatula device in most common use is the wooden AYRE'S spatula. These devices are not without their disadvantages, the AYRE'S spatula being difficult to manipulate without causing discomfort or injury to the patient and giving less than satisfactory results in obtaining adequate endocervical cell samples.

To address these problems, spatula devices that are more flexible have been developed, one of which is the well-known CYTOBRUSH spatula. The CYTOBRUSH is significantly better than the wooden spatula for collecting endocervical cells, but not significantly better for collecting and detecting metaplastic cells. These deficiencies in the CYTOBRUSH spatula may arise because of excessive flexibility.

It is an object of this invention to address these

apparent deficiencies.

Summary of the invention

This invention provides a medical spatula comprising a grip and a substantially planar blade including an open loop of a resiliently deformable material extending about the outer periphery of the blade and a lattice of spaced apart bars of a resiliently deformable material that arise from the peripheral loop and transect the body of the blade.

The spatula, in the preferred form of the invention, is adapted for use as a cervical spatula in that the periphery of the blade is shaped to conform to the shape of the average cervical os.

It is appreciated that the shape of the cervical os varies widely from woman to woman and that the shape and consistency of the tissue of the cervical os tends to vary, within the same woman, in dependence on her age, the state of her pregnancy (if any) and the phase of her menstrual cycle.

The spatula blade is therefore shaped in essence, to conform to an idealised cervical os. However, the flexibility of the blade is intended to assist in conforming the blade shape to any deviations from the idealised cervical shape that may be exhibited by an actual cervix when the spatula is used.

To this end, the blade is essentially triangular in plan outline, the end of the spatula being constituted by the apex of the triangular blade and the sides of the triangular blade arising from th apex being

concave in plan outlin .

All the plan outline corners of the triangular blade are rounded, the base corners being rounded more than the apex, in order to avoid possible discomfort or injury in use.

The bars making up the body of the blade may conveniently be constituted by a plurality of non-discrete lands spaced apart from one another by interposed grooves. Some or all of the grooves may be constituted by slots formed to extend through the plane of the blade.

In the preferred form of the invention, all the grooves are constituted by slots.

The blade and preferably the entire spatula, being the grip and the blade, are integrally formed from a resiliently deformable material such as injection moulded plastics, preferably low density polyethylene.

To assist in conforming to the shape of the cervix and also to maximise the scraping action of the blade, without thereby increasing the risk of injury, the blade is adapted to flex in the plane of the blade.

This can be done by tapering the blade either or both longitudinally and transversely.

In order further to maximise the scraping action of the blade, the peripheral edges of the blade may be relatively sharp in cross section.

The grip may be longitudinally tapered from the hand

grip end thereof to th point of attachment of the grip to the blade, the narrowing portion of the tapered grip being progressively more flexible up to the point of attachment of the grip to the blade. This is particularly appropriate for a spatula intended to be used as a cervical spatula.

Brief description of the drawings

In the drawings:

Figure 1 is a diagrammatic isometric view of a cervical spatula according to the invention;

Figure 2 is a plan view of the spatula of Figure 1;

Figure 3 is a side elevation of the spatula of Figure 1;

Figure 4 is a cross section through the blade on a line 4 - 4 in Figure 3;

Figure 5 is an enlarged view of one half of the section of Figure 4 (the circled area);

Figure 6 is a cross section on a line 6-6 in Figure 3;

Figure 7 is an isometric view of an alternative cervical spatula according to the invention;

Figure 8 is a diagrammatic isometric view of yet a further alternative cervical spatula according to th invention;

Figure 9 is a side elevation (partly in section) on a line 9-9 in Figure 8;

Figure 10 is an enlarged view of the area circled in Figure 9;

Figure 11 is a cross section through one half of the blade of the spatula of Figure 8 taken on a line 11-11 in Figure 8;

Figure 12 is a diagrammatic representation of the cervical spatula of the invention in use;

Figure 13 is a diagrammatic representation illustrating the positioning of the spatula blade in the cervical os; and

Figure 14 is a diagrammatic representation of the manner in which a cervical cytology sample collected with the spatula of the invention is deposited onto a glass slide.

Description of embodiments of the invention

The exfoliative cytology spatula illustrated in the drawings is a cervical spatula 10 that is intended for conducting PAP tests.

One of the difficulties faced by the practitioner in conducting PAP tests is to be found in the fact that the cervical passage, in most women, enters the vaginal passage at an angle as is illustrated in Figure 12. However, the practitioner is obliged to insert and manipulate the cervical spatula coaxially with the

vaginal passage and to make the best of keeping the insertion end of the spatula in constant engagement with the cervical os.

This is very difficult to achieve during the sampling process, since rotation of the spatula is required.

As a result, the angular deviation of the cervical and vaginal passages makes it difficult to obtain endocervical cells when conducting PAP tests with rigid spatulas such as the AYRE'S spatula.

In order to overcome this difficulty, the CYTOBRUSH spatula was developed. It includes a pair of flexible vanes extending on either side of a nose adapted for insertion into the cervical os during the conduct of the PAP test. Unfortunately, the flexibility of the vanes makes it difficult to obtain metaplastic cells.

It is with these difficulties in mind that the cervical spatula of the invention was developed, the intention being to provide a spatula with sufficient deformability in or parallel to the principal axis of the spatula to permit substantial conformity with the shape of the cervical os during rotation of the spatula, but yet sufficient rigidity in the blade plane to perform an adequate scraping operation without hurting or injuring the patient.

The cervical spatula 10 of the invention includes a grip comprising a round hand grip 12 on the end of a thin insertion rod 14. The grip 12 is provided with indentations 16 that serve as grip formations. The insertion rod 14 is fluted by means of longitudinally extending indentations 18 which serve to enhance the

rotational rigidity of the insertion rod 14 without sacrificing the longitudinal flexibility that is required for the proper conduct of PAP tests.

At its opposite end, the spatula 10 is formed with a flat planar blade 20.

The spatula is integrally moulded from low density polyethylene.

The blade 20 is constituted by a grille or lattice of spaced apart bars 22 bounded by a closed loop 24 of material that defines the outer periphery of the blade 20. The spaces 23 between the bars 22 are formed as open slots that extend through the body of the blade 20, as can be seen more clearly from the cross sections in Figures 4 and 5.

The blade 20 is symmetrical about a central axis (which is co-axial with the principal axis of the grip 14) and the blade 20 is essentially triangular in plan outline. The insertion end 26 of the spatula is constituted by the apex of the triangular blade and the sides of the triangle arise from the apex to provide a heart-shaped or arrow head-shaped spatula blade 20.

The insertion end of the blade 20 is rounded in plan to define a nose 28 that is designed to enter the cervical os during sampling.

The peripheral rim 24 of the blade 20 curves symmetrically away from the nose 28 on either side thereof. The concave curved areas 29 of the rim 24 is shaped to be complemental to the entrance and ecto-cervical area of the cervix.

All surfaces of the blade 20 are rounded in order to minimise the risk of injury, pain and discomfort.

However, along the line of intersection between the principal plane surfaces of the blade 20 and the periphery 24, the angle of intersection is acute and the point of intersection is relatively sharp. This is to provide relatively sharp rim edges 25 that are designed to maximise cell accumulation during sampling. For the same reason, the same design is used along the lines of intersection between the principal plane of the blade 20 and the edges of the bars 22 to provide sharp edges 27 in these areas as well.

The cervical spatula 10.1 illustrated in Figure 7 is similar to the cervical spatula 10 described above with the exception of a smooth insertion rod 14.1 and hand grip 12.1.

The cervical spatula 10.2 illustrated in Figures 8, 9, 10 and 11 differs from the cervical spatula 10 and 10.1 described above in several respects. Not only are the insertion rod 14.2 and the hand grip 12.2 different in the spatula 10.2, but the blade 20.2 differs markedly. Instead of being slotted, the blade 20.2 is merely grooved so that the bars are constituted by a number of side-by-side lands 22.2 that are spaced apart from one another by grooves 23.2 interposed between the lands 22.2.

In Figures 9, 10 and 11, this aspect is more clearly illustrated. In these drawings, it can be seen that the grooves 23.2 do not extend fully through the body of the blad 20.2. The grooves 23.2 are, however,

formed on either side of the blad 20.2.

The spatula 10.2 will be more rigid than the spatulas 10 and 10.1 described above if similarly dimensioned and made from similar materials.

The biconcave triangular shape of the blade 20 is designed to permit selective acquisition of cells from the endocervical and ecto-cervical areas of the cervix. The peripheral rim 24 of the blade 20 being constituted, essentially, by a loop of resiliently deformable material, is complaint enough to accommodate most variations in the shape of the cervix.

The blade 20 is substantially planar, but as can be seen from the side elevation of Figure 2 and the cross sections of Figures 4 and 5, the blade is tapered in two directions in cross section.

In longitudinal cross section, the blade 20 tapers towards the nose 28. The opposing upper and lower plane surfaces of the blade converge from the thicker part of the blade 20, which is the end at which it is attached to the insertion rod 14, towards the nose of 28.

In transverse cross section, the blade 20 is inversely tapered so that, in cross section, it is thinner in the middle than it is at the sides, the thickest areas of the blade 20 being the wings 30 that define the base of the blade 20.

In addition, the spatula grip which tapers from the hand grip 12, through the insertion rod 14 to the point of attachment to the blade 20, becomes progressively

more flexible up to the point of attachment of the grip to the blade 20. This allows the insertion rod 14 to flex progressively more along its length in order to accommodate the angular misalignment of the cervix with the virginal passage, even during rotation of the spatula. This aspect is illustrated diagrammatically in Figure 12 which illustrates the cervical spatula 10 of the invention in use. In this drawing, the spatula 10 of the invention is inserted into the vagina of a patient through a speculum 32 that permits an unobstructed view of the cervix 34 of the patient.

The practitioner, having inserted the blade 20 through the speculum 32 up to the point where the blade 20 is correctly positioned in the cervix 34, rotates the spatula 10 between her thumb and forefinger to collect a sample of cervical cells.

During rotation of the spatula 10, the insertion rod 14 flexes to accommodate the misalignment of the cervix and the vaginal passage. In addition, the peripheral rim 24 of the blade 20 flexes during rotation in order to accommodate any variations in the shape of the cervix 34 that deviate from the shape of the blade 20.

The rim 24 flexes principally in the plane of the blade 20 with the bars 22 providing relatively little resistance to such flexing. The bars 22 do not detract significantly from the compliance of the peripheral rim 24, yet they contribute to the collection of cells.

During rotation of the spatula 10, in the cervix 34, the blade 20 also flexes in the plane of the blade 20. The degree of flexing is not great and the blade 20 is intended to twist ever so slightly about the principal

axis of the spatula 10 in helical fashion.

The blade 20, in twisting like this, performs a slightly more aggressive scraping action within the cervix 34, since twisting of the blade presents the edges 25 of the peripheral rim 24 of the blade 20 at a slightly more acute angle of attack during rotation of the blade 20 within the cervix 34. Twisting of the blade 20 also misaligns the bars 22 slightly and presents the edges 27 of the bars to the cervical tissue to a greater extent.

The diagram of Figure 13 illustrates the location of the blade 21 within the cervix 34 in greater detail. In this drawing it can be seen how the tip of the blade 20 penetrates deep into the cervix 34 in order to collect endo-cervical cells. The concave sides 29 of the blade 20 extend from within the cervix to the area adjacent to the entrance of the cervical os, to collect progressively less endo-cervical cells and progressively more ectocervical cells from the central regions of the blade 20 towards the wings 30 at the base of the blade 20.

The blade 20 is sufficiently compliant to accommodate nulli- and multigravidae cervixes.

The spatula 10 of the invention has additional advantages. Not only does it permit the selective acquisition of cells from the endocervical and ecto-cervical areas, but it allows deposition of the cells on a glass slide for instance, in a similar fashion.

This aspect is illustrated in Figure 14.

Flat blade spatulas suffer from the disadvantage that the collected sample adheres preferentially to the flat surface of the spatula. In consequence a fair amount of manipulation is required in order to force the sample to adhere to the slide in preference to the spatula to deposit cells collected during the PAP test on the glass slide. Often this results in the practitioner smearing the cells around on the glass slide and losing the original location of the cells in the eventual sample.

The spatula 10 of the invention seeks to overcome this deficiency by permitting more effective deposition of the cells onto a glass slide 36 without the need for excess manipulation.

This is done by using capillarity to assist in depositing the sample onto the slide. When the blade 20 is placed flat on a glass slide, a gap tends to be left between the slide and the tapered nose 28 of the blade 20. This gap is in communication with and co-operates with the slots 23 between the bars 22 in the grille defining the surface of the blade 20. The capillarity of these co-operating capillary spaces assists in drawing the sample from the blade 20 when, in depositing the collected cells on a glass slide, the practitioner draws the blade 20 longitudinally along the glass slide (in the direction of the arrows).

In the process, the practitioner is not required to smear the sample. This means that the blade can be drawn straight down the glass slide, depositing endo-cervical cells in the centre (40) of the sample and ectocervical cells on either side (42) thereof. This will allow the pathologist to examine the slide knowing

that cells can be distinguished as to their origin.

The spatula 10 of the invention therefore has the advantage that it permits the selective acquisition of cells from the endocervical and ecto-cervical areas. In addition, it allows deposition of the cells in a similar fashion.

Claims

1. A medical spatula (10) comprising a grip and a substantially planar blade (20) characterised by the provision of an open loop (24) of a resiliently deformable material extending about the outer periphery of the blade (20) and a lattice of spaced apart bars (22) of a resiliently deformable material that arise from the peripheral loop (24) and transect the body of the blade (20).

2. A spatula according to claim 1 that is adapted for use as a cervical spatula (10) in that the periphery (24) of the blade (20) is shaped to conform to the shape of the average cervical os, the blade (20) being triangular in plan outline, the end (28) of the spatula being constituted by the apex (28) of the triangular blade (20) and the sides (29) of the triangular blade arising from the apex being concave in plan outline.

3. A spatula according to either of the preceding claims in which the bars (22) are constituted by a plurality of non-discrete lands (22,2) spaced apart from one another by interposed grooves (23.2).

4. A spatula according to claim 3 in which at least some of the grooves (23.2) are constituted by slots (22) formed to extend through the plane of the blade (20).

5. A spatula according to claim 4 in which all the grooves are constituted by slots (23).

6. A spatula according to any one f the preceding claims in which the blade (20) is integrally formed from a resiliently deformable material.

7. A spatula according to claim 6 in which the blade (20) and grip are integrally formed from a resiliently deformable material.

8. A spatula according to any one of the preceding claims in which the blade (20) is adapted to flex in the plane of the blade (20), the blade (20) being tapered in longitudinal cross-section, the opposing plane surfaces of the blade (20) converging from a thicker part of the blade (20) at the point of attachment of the grip to the blade (20) towards a thinner part of the blade (20) at the end of the blade (20) opposite the point of attachment of the grip to the blade.

9. A spatula according to any one of the preceding claims in which the blade (20) is adapted to flex in the plane of the blade (20), the blade (20) having a double taper in transverse cross-section in that the opposing plane surfaces of the blade (20) converge from the longitudinally extending edges of the blade (20) towards the longitudinally extending centre line of the blade (20).

10. A spatula according to any one of the preceding claims in which the peripheral edges (25, 27) of the blade (20) are relatively sharp in cross section.

11. A spatula according to any one of the preceding claims in which the grip is longitudinally tapered

from a hand grip (12) end thereof to the point of attachment of the grip to the blade (20), the narrowing portion (14) of the tapered grip being progressively more flexible up to the point of attachment of the grip to the blade (20).

12. A cervical spatula according to any one of the preceding claims.

13. A spatula substantially as described in this specification with reference to the accompanying drawings.

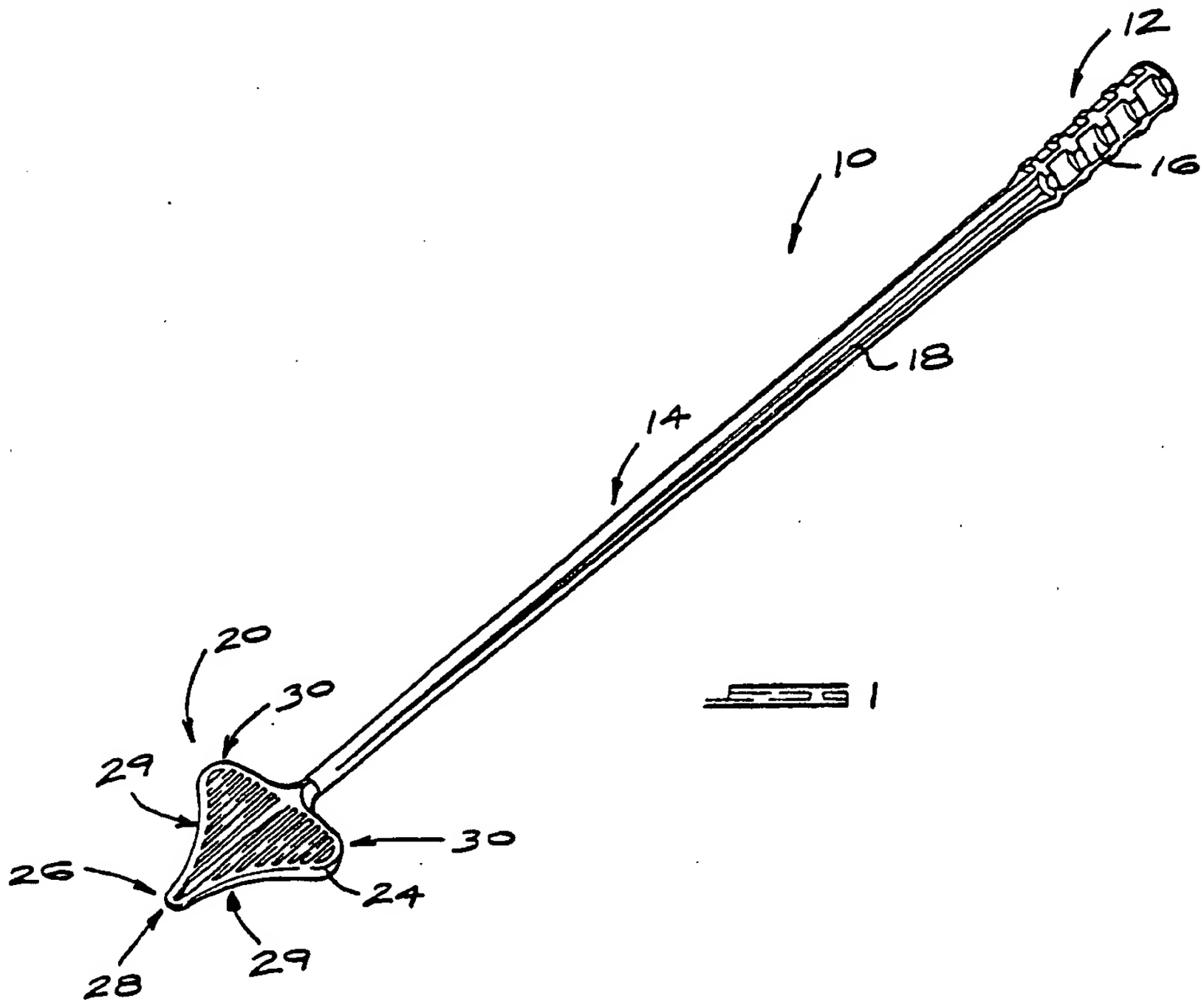


Fig 1

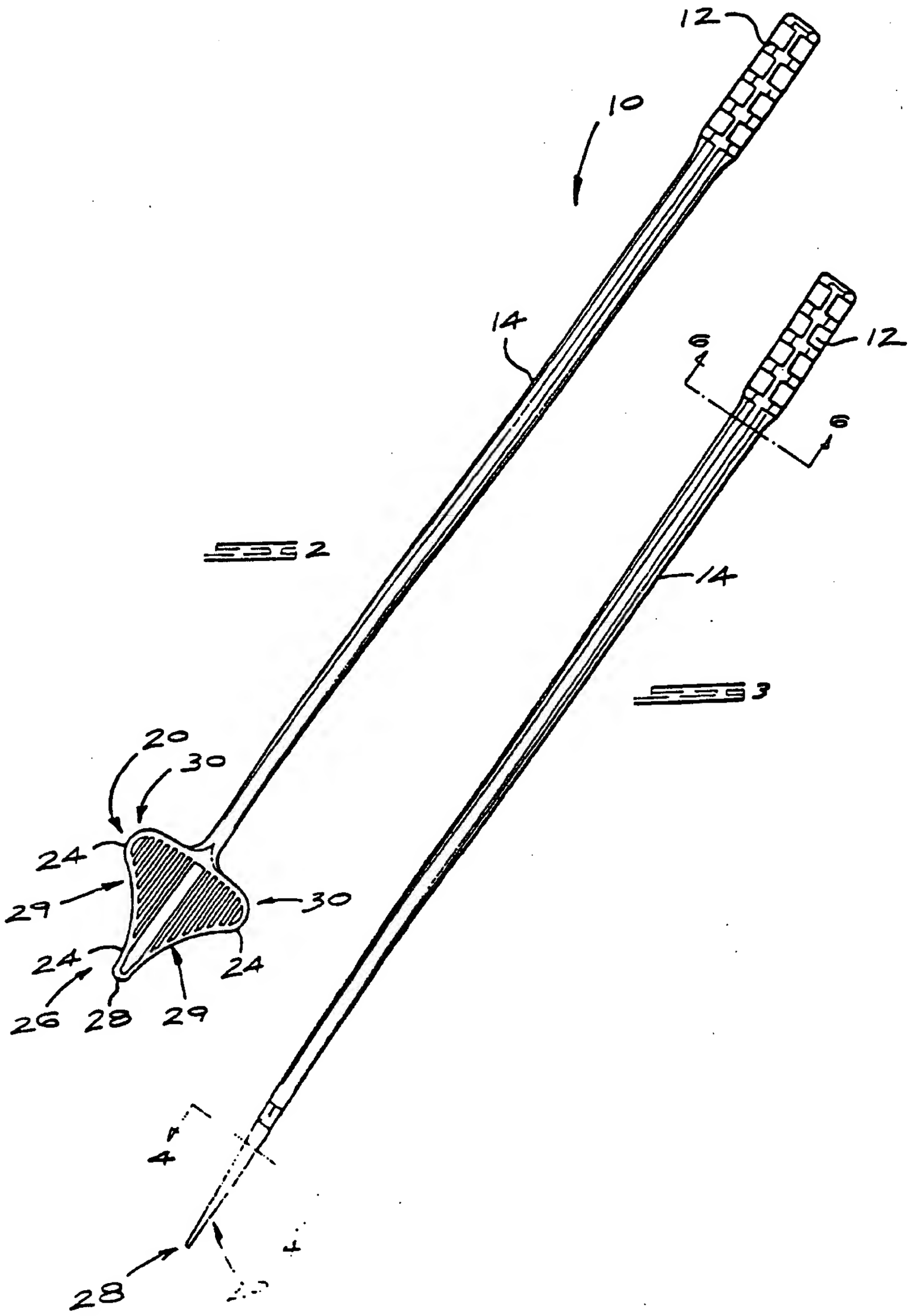


FIG 2

FIG 3

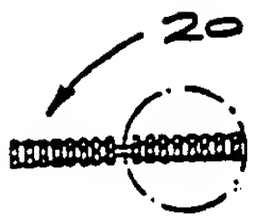


Fig 4

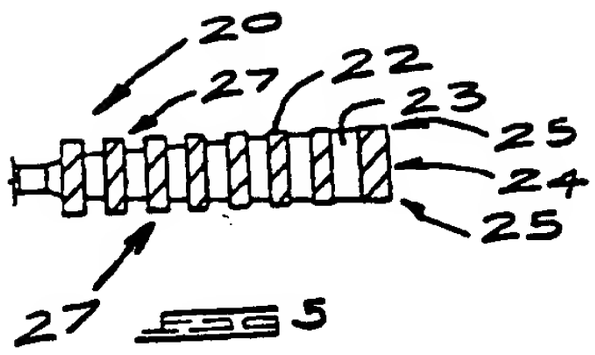


Fig 5

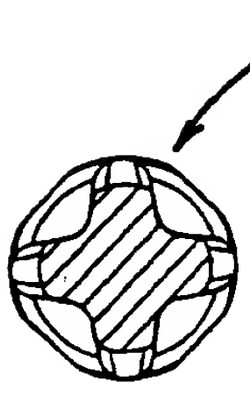


Fig 6

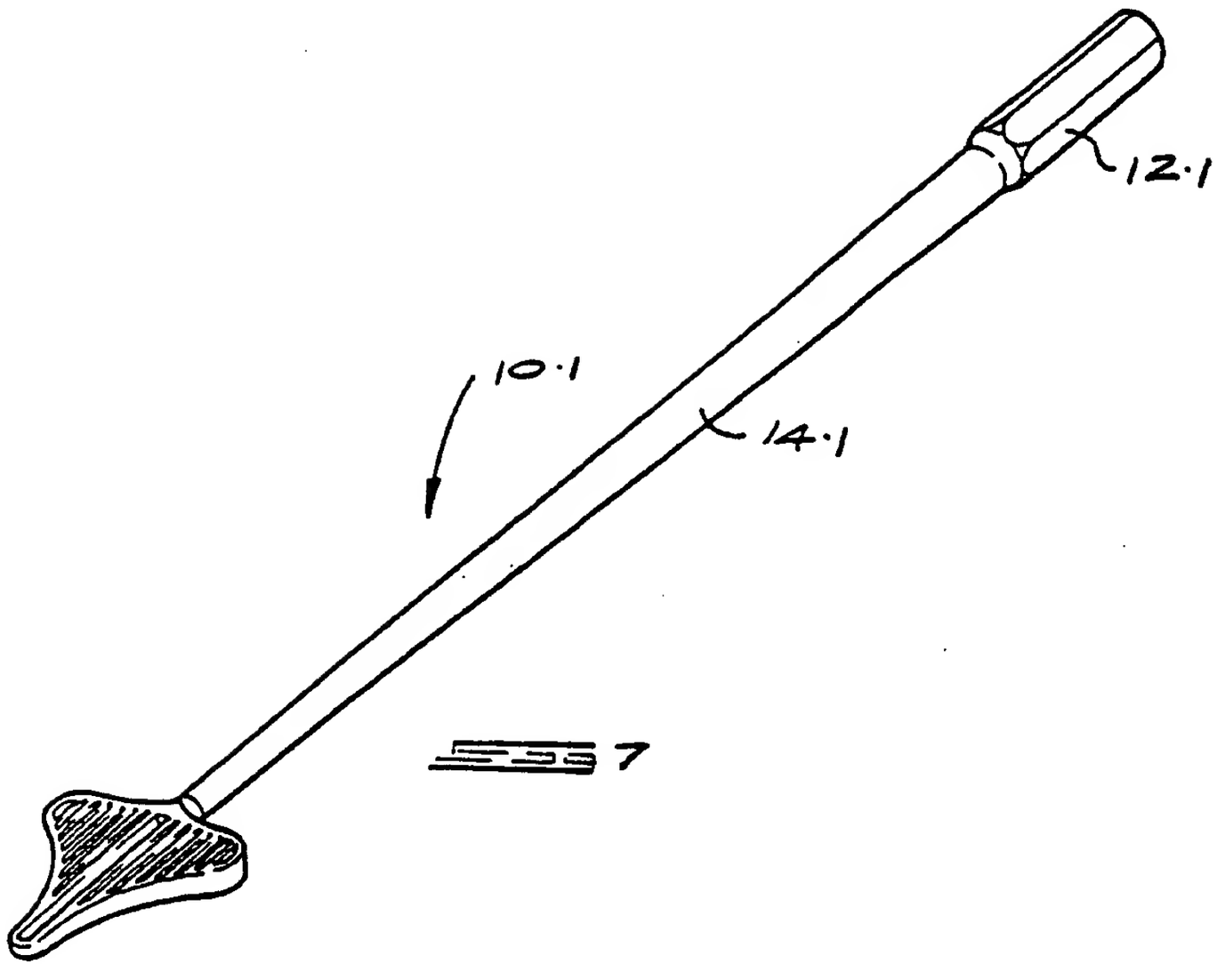
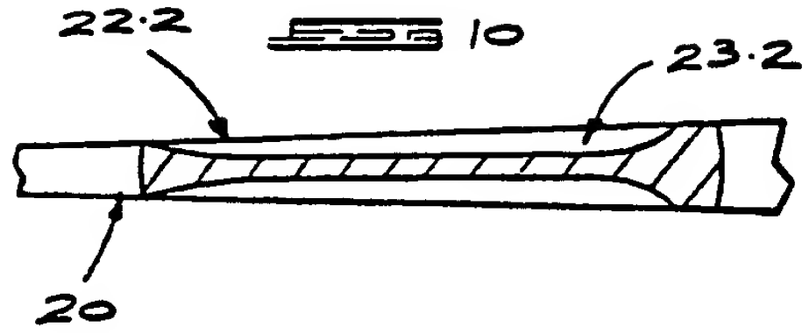
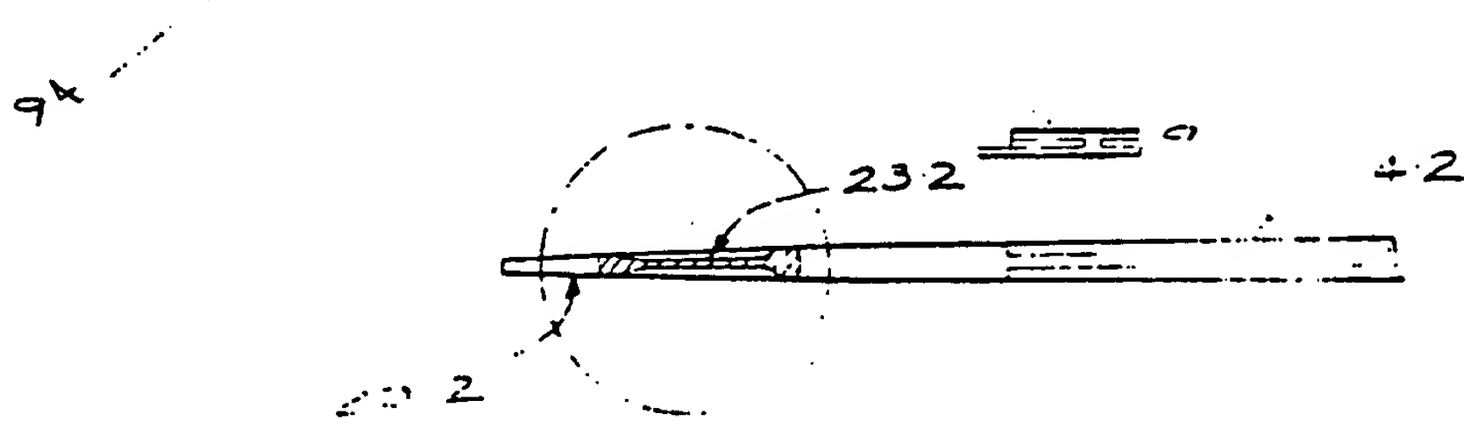


Fig 7


22.2
10
23.2
20


11

12.2
14.2
10.2
8
11
23.2
9
22.2
20.2
11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4.2
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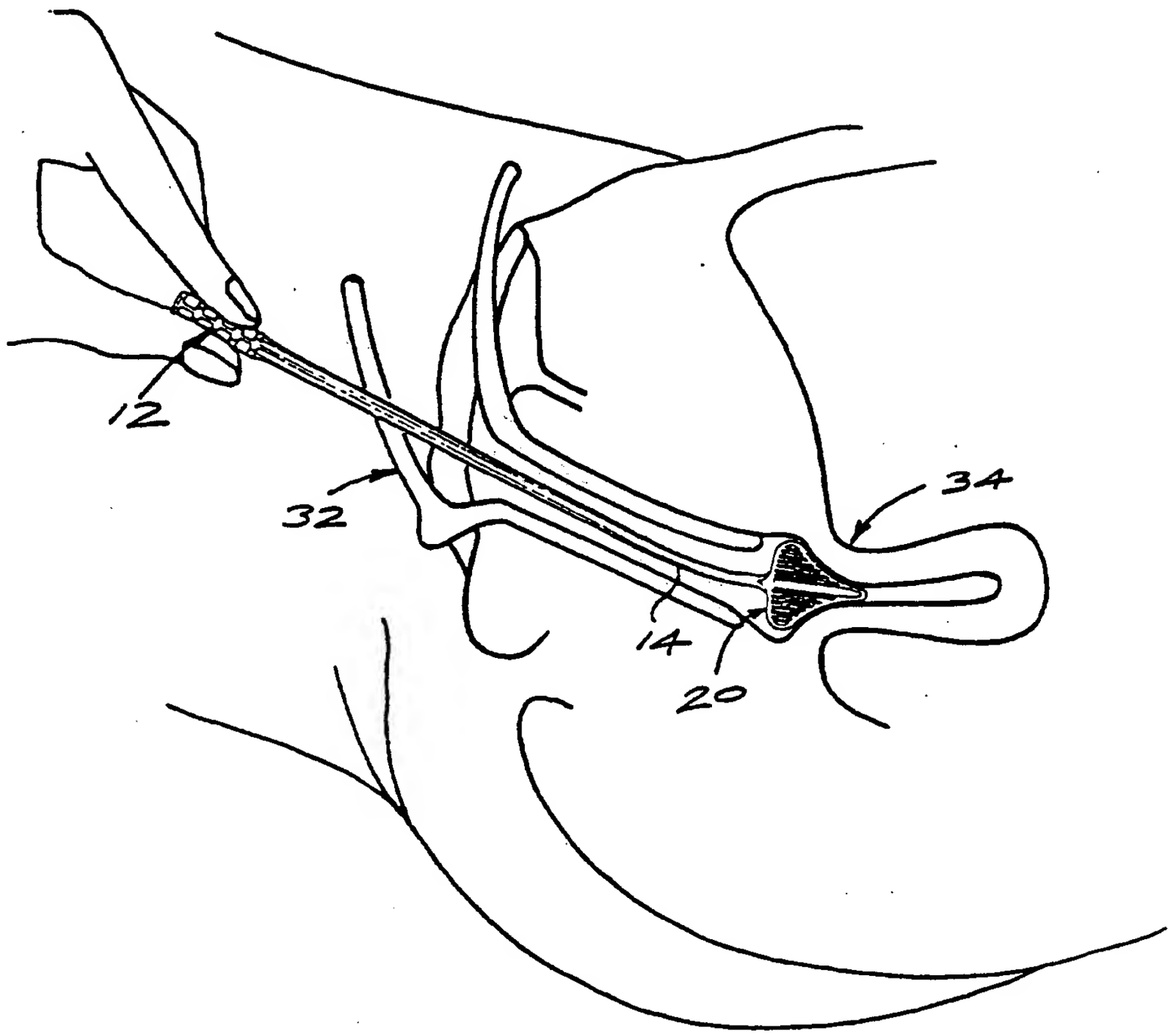

FIG 12

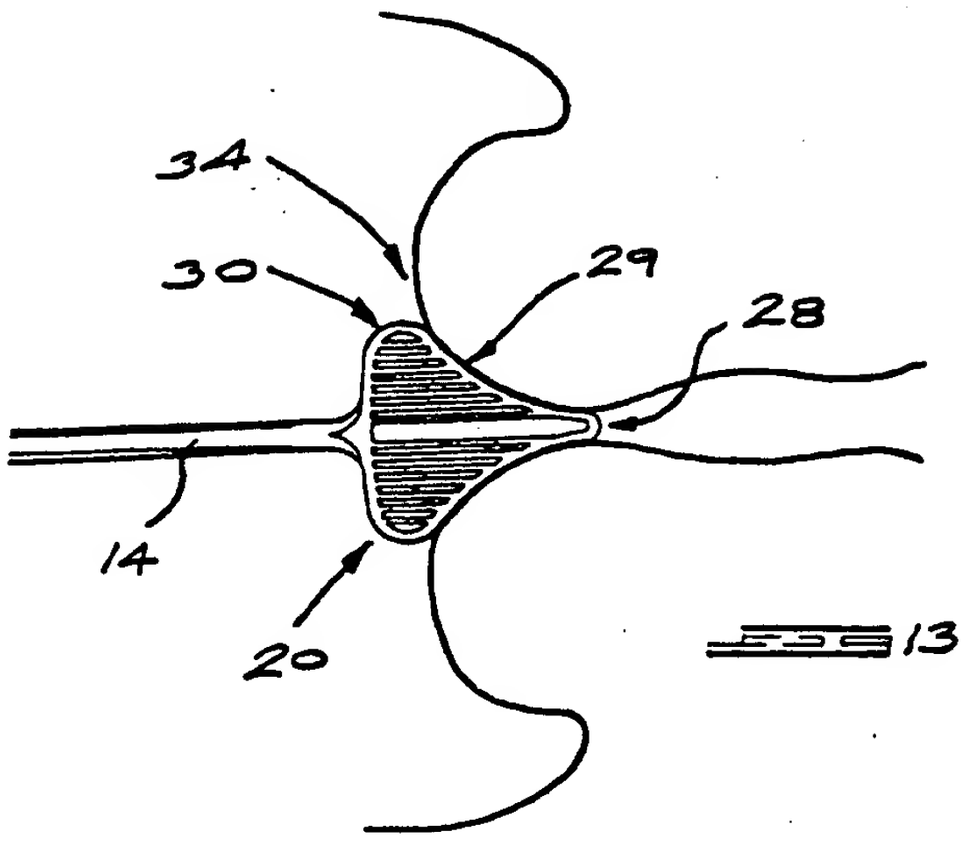

FIG 13

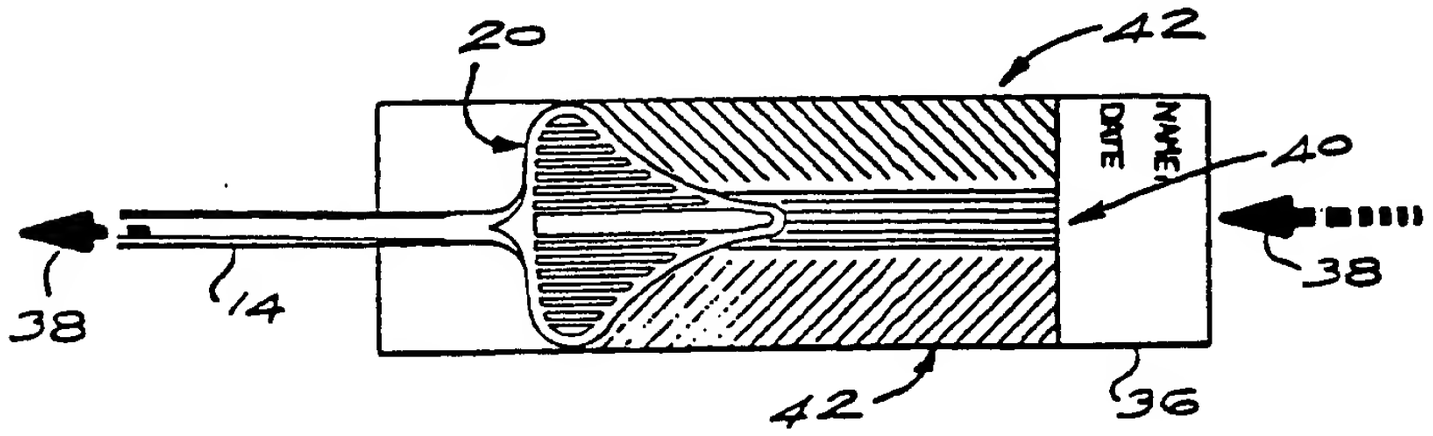

FIG 14

INTERNATIONAL SEARCH REPORT

Inf. tional Application No
PCT/GB 98/03431

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 94 09704 A (LONSTEN PTY LTD ;STENNING HENRY MARTIN (AU)) 11 May 1994 see page 7, line 15 - page 10, line 24; figures 1,2	1,13
A	WO 93 01749 A (LONSTEN PTY LTD) 4 February 1993 see abstract; figures 1,3	1,13
A	EP 0 106 461 A (PISTOFIDIS GEORGE) 25 April 1984 see page 3, line 35 - page 4, line 24; figures 1,2	1,13
A	US 2 471 088 A (AYRE J E) 24 May 1949 see the whole document	1,13

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Date of the actual completion of the international search	Date of mailing of the international search report
24 February 1999	02/03/1999

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Inl tional Application No
PCT/GB 98/03431

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
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